

# Identifying, Understanding, and Communicating Medical Device Use Errors: Observations from an FDA Pilot Program

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## Abstract

The U.S. Food and Drug Administration (FDA) attempts to identify and understand new risks associated with medical device use; communicate information and recommendations to device users; help manage known risks by providing strategies to facilitate safe use; guide manufacturers to improve design, labeling, and training to address known risks; and guide users to make smart decisions about the acquisition and introduction of new technology. To identify the risks associated with medical devices, FDA has begun development of a device error reporting system, the Medical Product Surveillance Network (MedSun). The purpose of MedSun is to rapidly detect and understand previously unknown and serious problems, particularly close-call events. The heart of MedSun is its relationships with a relatively small, specifically trained and motivated group of workers who are focused on identifying device-related issues. This allows FDA to quickly react to the potential problems and identify the causes, contributing factors, and magnitude of a new risk. MedSun also serves as a virtual laboratory for problem research by focusing on certain devices, units, and users. This provides FDA with a better understanding of device problems, especially the human factors issues. This paper describes the development, implementation, and progress of the MedSun program.

## Introduction

Since February 2002, the U.S. Food and Drug Administration (FDA) has been working collaboratively with a relatively small, well-trained representative sample of health care institutions to understand and share problems with the use of medical devices. This program, named the Medical Product Surveillance Network (MedSun), has three major objectives:

1. Rapidly identify and understand problems with the use of medical devices,
2. Provide a virtual laboratory for research into understanding device problems, and
3. Provide actionable feedback to health care professionals.

This paper will discuss FDA's approach in developing the MedSun adverse event reporting program, including the steps to create a successful device reporting system, barriers to attaining each step, and the strategies implemented to

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overcome them. It will then present the preliminary results obtained with the system and future plans.

## **Building a new reporting system**

The Federal Food, Drug and Cosmetic Act (the Act), Section 519, mandates that all manufacturers of medical devices must report device-related deaths, serious injuries, and certain types of malfunctions to the FDA.<sup>1</sup> Part (b) of this section also stipulates that “device user facilities” must report medical device related deaths to FDA and to the manufacturer and report serious injuries to the manufacturer. User facilities are defined as hospitals, nursing homes, outpatient treatment centers, outpatient diagnostic centers, home health agencies, and emergency services. Approximately 40,000 user facilities are affected by this law, which is implemented by the Code of Federal Regulations, 21 CFR Part 803.<sup>2</sup>

FDA uses these user-facility reports, along with the information received from manufacturers and consumers, to identify signals of emerging public health problems with the use of medical devices. FDA then strives to understand these problems and to develop means to address them, including product recalls, Public Health Notifications, working with manufacturers to institute labeling and design changes, and working with professional organizations when the best solution to a problem may not be a regulatory solution.

However, over the years FDA has not received the expected number of reports from user facilities. There are numerous reasons why user facilities may underreport device problems. More importantly, the reports submitted tend to lack substantive information to allow FDA to understand the problem or issue. For example, there is often no description of exactly how the device was used or programmed, the serial numbers or lot numbers, the patient outcome, or preexisting clinical problems that could have contributed to the event. This type of information is important for FDA to discern exactly what caused the problem and what types of solutions it should put forth to keep it from happening again.

To overcome these obstacles, FDA decided to develop a program that would facilitate a more collaborative relationship with the clinical community. This would allow FDA to understand the causes and contributing factors associated with problems health professionals have using medical devices. FDA also wanted to encourage the reporting of “close-calls” with the use of medical devices so it could become more proactive in addressing device issues before a death or injury occurs.

In 1996, FDA began the initial research that would lead to the development of MedSun. The barriers to reporting were explored, both those within a reporting institution and those that affected the institution’s ability to send the report to FDA. This research is ongoing as FDA continues to implement the MedSun reporting pilot program.

A key factor in the entire MedSun research, development, and implementation process is that a contractor acts as an intermediary and performs many key

functions. In addition to aiding in the research and development aspects of MedSun, the contractor performs the recruiting of health care institutions and MedSun representatives, carries out the day-to-day program operations and provides contact with MedSun participants. The contractor is critical to helping FDA overcome barriers to reporting and has been successful in building positive relationships with MedSun reporters. The number of reports received continues to increase without the need to offer reporter anonymity (i.e., all reports are submitted with both the facility and the reporter identified). In addition, the quality and completeness of reporting is better assured without anonymity because contractor staff are able to speak directly with the facilities' MedSun representatives to clarify event information before the report is submitted to FDA. Additionally, FDA staff may have further questions about an incident after receiving the report from the contractor. Knowing the origin of the report facilitates FDA's efforts to contact the reporter for timely follow-up.

In planning for the new collaborative reporting system, FDA worked with the contractor to outline the steps that must occur to establish the program (MedSun). It was postulated that completion of these steps would successfully establish MedSun in each participating facility, increase the awareness of staff to the importance of reporting within the institution, and generate complete and useful error reports from those facilities. The steps are described below.

## **Steps to reporting, barriers to reporting, and strategies to overcome barriers**

The first four steps focus on identifying the reporting facilities for the MedSun program and selecting and working with the individuals who report to FDA using the MedSun reporting software. These steps build the foundation of the program.

### **Step 1: Identify a sample of medical facilities.**

After it became mandatory for user facilities to make device-related adverse event reports, FDA attempted to train user facilities to report errors by establishing a network of trainers at the FDA District offices. While this program showed some initial success, it proved impossible to sustain over time given the number of facilities affected by the law (40,000+) and lack of FDA resources. Based on a limited resource model, FDA decided it could overcome barriers to training 40,000+ reporting facilities by developing a sample system of well-trained reporters to participate in MedSun. This notion was further validated when Congress in 1997 modified the legislation dealing with user facility reporting in the Food and Drug Administration Modernization Act.<sup>3</sup> In terms of user facility reporting, the new law requires FDA to move from a system of mandatory, universal reporting to one based on a representative sample of user facility reports.<sup>1</sup> However, universal reporting is still in effect until an implementing regulation is developed.

To select the sample of facilities that would be asked to participate in the MedSun pilot program, the 2003 American Hospital Association (AHA) database listing of hospitals was used as the sample frame. From this frame large, medium,

and small facilities as well as academic and nonacademic institutions from each region of the country have been recruited. Both volunteer sites and sites that have been selected through the sample are included in MedSun. The selected sites represent the various types and sizes of facilities that are obligated to make reports of deaths and serious injuries with medical devices; therefore, we expect the types of reports received from them to be representative reports.

**Step 2: Select MedSun representatives from each site and facilitate the movement of information about medical devices to the representatives.**

The barrier to the movement of information within a facility is that an adverse event report made by a health professional can be stopped along its path within the institution at any number of points, including receipt by the immediate manager. This person sometimes does not want problems reported under his or her “watch.” This typically occurs in organizations that have a “blaming” culture when errors occur. If the report has been stopped at some point in the system, the facility’s MedSun representative will not have the report to send to FDA, which has little control over the culture of the facility. But, in organizations where the report does move through the facility, there still may be a barrier to the information reaching the MedSun representative. There may be compartmentalized functions within the hospital, thereby causing some types of reports to go to the quality manager for resolution, some to go to a patient safety committee, etc. Therefore, even when reports move through the facility, no one person may have all the information in which FDA is interested.

Because FDA can have little effect on the reporting culture of a facility, attention was focused on facilitating the flow of information by overcoming the barrier of “compartmentalism” of reports in the facilities. Instead of relying on only one person to be a MedSun representative, it was decided to recruit two individuals from different areas of each organization to be MedSun representatives. These representatives would be responsible for sending reports from the institution to FDA through the MedSun software. This increases the likelihood that FDA would learn about more problems with medical devices because data could be accessed from different parts of the facilities. Risk managers were selected as the primary MedSun representatives at each site since they most often have responsibility for adverse event reporting. Because of their interaction with medical devices, the biomedical or clinical engineers at each site were also recruited as MedSun representatives. Some facilities also ask to include quality managers or patient safety managers.

**Step 3: Train the MedSun representatives to write complete and accurate adverse event reports.**

Each MedSun representative attends a 3-hour training program that includes discussion of all aspects of the program, including the types of information that FDA requires to analyze the report.

Further details about a report can be obtained through follow-up calls from the contractor and FDA to the MedSun representatives. This step has the added benefit of training the health professional who made the initial report in the facility. As the MedSun representatives seek out the initial reporters to obtain answers to the follow-up questions, the health professionals (initial reporters) learn what types of information they need to include in their next report.

#### **Step 4: Motivate the MedSun representative to send the report to FDA and supply actionable feedback.**

There were several barriers that we needed to address to motivate the moving of reports outside the institution. These were: burden of reporting, liability concerns, and lack of feedback.

To aid in overcoming the perception of reporting as being burdensome, we designed a secure, web-based system that is faster, more flexible, and easier to use than a paper-based system. The MedSun software application was designed to meet security and privacy specifications while being easy to access and use.

To overcome the barrier of the fear of liability, the MedSun representatives are trained on the statutory and regulatory authority FDA has to protect the data it receives. It is beyond the topic of this paper to describe these protections in detail. Interested readers may contact the authors if more information about these protections is desired.

To overcome the feedback issue, we have developed a number of tools to supply actionable feedback to the sites. These tools also serve to motivate reporting. They are described below:

**MedSun News.** A monthly newsletter is sent to all MedSun representatives. It includes summaries of reported events (with no patient or hospital identifiers), safety resources, articles written by MedSun and other FDA staff, and safety tips on how to avoid problems with the use of devices (prompted by the reports sent to MedSun). MedSun participants have reported using the newsletter to aid in detecting device problems at their own facilities and to increase their staff's awareness of device-related problems and solutions.

**MedSun Clinical Engineering Conference.** The MedSun Clinical Engineering Audio-Conferences provide a means for FDA to speak and to learn from biomedical and clinical engineers about medical device issues of interest to them. MedSun participants interact with experts from both FDA and other safety organizations to help them respond to regulatory requirements (e.g., JCAHO's patient safety alarm goals) or to better understand complex issues (e.g., the effect of electromagnetic interference on device performance). Transcripts from the conferences are available to the public.<sup>4</sup>

**MedSun Participant Web Site.** In February 2004, the MedSun Participant Web Site was made available to MedSun participants. The web site enables participants to see what is new in MedSun, search for report information from the MedSun News, view transcripts and slide shows from past Clinical Engineering Audio-Conferences, and search a custom medical device recalls database. There

are three levels of access—for the public, for MedSun sites, and for MedSun authorized reporters.<sup>5</sup>

**FDA Patient Safety News.** FDA Patient Safety News (PSN) is a televised series for health care personnel that is carried on satellite broadcast networks aimed at hospitals and other medical facilities across the country. It features information on new drugs, biologics and medical devices, FDA safety notifications and product recalls, and ways to protect patients when using medical products. It is also available for viewing on the PSN website.<sup>6</sup>

**Collaboration with ECRI.** ECRI (formerly the Emergency Care Research Institute) is a nonprofit health services research agency with expertise in medical product evaluations and technology assessments.<sup>7</sup> The MedSun contractor and FDA staffs use ECRI services to provide supportive research on select reported device problems. The contractor staff sends ECRI deidentified MedSun reports. ECRI reviews the information and offers analysis and recommendations based upon information from their own analysts, their database findings, and risk communications they have written about the subject. The contractor then provides this information to the site that generated the report to aid it in further understanding the problem.

**MedSun Participant Conferences.** A 2-day user conference is held every year where MedSun participants share knowledge about their own programs and have time for informal discussions with other members from all over the U.S. Speakers are selected from FDA administration, MedSun facilities, risk management and biomedical engineering societies, manufacturer groups, and other respected safety organizations. Conference attendees learn how specific MedSun reports have affected FDA's response to adverse events in the previous year and what upcoming MedSun and other FDA programs are planned for the future.

**Device Safety Exchange (DS-X).** The goal of DS-X is to create a collection of best practices and resources that MedSun representatives, as well as all clinical sites in the United States, may access online. It is currently under development by FDA and will be structured to promote knowledge sharing. MedSun sites will be encouraged to send in success stories of ways in which they have improved device safety in their facilities. Other sites may then use these stories to create projects to improve device safety in their own facilities.

So, while FDA is still in the early phase of learning what motivates the MedSun representatives—primarily risk managers and biomedical engineers—to report to MedSun, good progress has been made in training and motivating these “upper levels of reporters.”

The final three steps in the MedSun program involve working with the “front-line” reporters in health facilities—the health professionals who use medical devices as part of their daily routine. The goal of these steps is to improve reporting from health professionals within their own facilities. Achieving this goal has been more difficult for FDA because the relationship FDA establishes via MedSun is with the MedSun representatives in the facility and not with the entire

staff. FDA has approached these final three steps by exploring the barriers to reporting within institutions and then developing a variety of tools for the MedSun representatives to use to overcome barriers within their own institutions. The representatives may select those tools that will be best received by their particular facility culture.

Following is a discussion of the barriers that must be overcome to improve device users' recognition of medical device adverse events, motivate users to report those events, and train users to write complete and accurate reports about the events. The tools developed—and those under development—to overcome these barriers are all targeted at these three areas.

### **Step 5: Improve users' recognition of medical device adverse events.**

In order to be truly successful, MedSun needs to successfully complete this step. If the user does not recognize that a patient problem may be related to the use of a medical device, a report will not be generated and sent to the risk manager or the biomedical engineer (the MedSun representatives). FDA has conducted focus groups with physicians and nurses and has learned that the health professionals often do not realize the breadth of the medical devices they use. They accept device problems as part of their daily function and expect to have to perform “workarounds” as part of their daily routine. They don't report the catheter that breaks—they just get another one. Alternatively, they may not realize that the problem they have in using a device may be due to poor device design. Thus, usage problems may go unreported.

Additionally, it may not be apparent that a problem may be due to the unanticipated interaction of two otherwise normally functioning devices. If health professionals are not trained to look for these types of interactions when something unusual happens with a device, serious device-device interactions are not discovered.

### **Step 6: Motivate users to report device adverse events within their own institutions.**

The health professionals in the focus groups reported that they are not motivated to report problems for many reasons. The three main reasons are: a) they are afraid of being blamed for making a mistake, b) they are embarrassed about having made what they perceive to be a usage error—in this case, they internalize feelings of shame rather than realize that the device design or the organization's systems are really at the root of the problem, and c) clinicians report they are just too busy with the pressures of the day to stop to make the report.

### **Step 7: Train users to write complete and accurate reports about medical device events.**

Clinicians report that it is not unusual for staff to receive training on the facility's incident reporting system only once (during orientation) with brief updates annually thereafter. Little training is given to the staff on how to



communicate all the details required for an outside agency (such as FDA) to understand what happened during a medical device related incident.

### **Tools developed in MedSun to aid in overcoming the reporting barriers in steps 5, 6, and 7**

The tools developed to improve the reporting behavior of health professionals within the facilities have all been designed to address the barriers to achieving steps five through seven. Under contract to FDA, ECRI developed training materials for the MedSun representatives to train health professionals to recognize the complex relationship between medical devices and patient care. This tool presents a series of slides with an accompanying script. The MedSun contractor and FDA are currently developing another series of slides (with script) that focuses on the importance of health professionals reporting device problems within their facilities and the type of information needed to make an actionable report. A short video is being produced that depicts a device-related adverse event and demonstrates why it is important to report such incidents within the facility. Thus, each MedSun site will have a selection of materials to use to train and motivate their staff to identify device-related adverse events and to report them within their institutions.

To provide visual reminders to hospital staff about the use of medical devices in their daily work, FDA worked with a graphics company to produce a set of five posters that may be hung in the facilities. These posters address a variety of topics, including the importance of reporting device-use problems. These posters are provided to the MedSun representatives upon request.

Additionally, the facility health professionals receive indirect training on writing good reports through the follow-up questions they are asked by the MedSun representatives.

### **Current status**

Data collection through the MedSun Internet web site began with 25 facilities in February 2002. Participation in the program has grown from the initial 25 facilities to over 280 in July 2004. Coverage has spread geographically from locations on the East Coast to facilities throughout the United States. The members are primarily hospitals, with 17 nursing homes also participating. In order to obtain device-problem reports from a number of practice areas, recruitment efforts in 2005 will focus on including hospitals that also have home health agencies, outpatient diagnostic and treatment facilities, and emergency services associated with them. FDA believes that around 350 may be the ideal number to allow for a balance among the types of facilities enrolled, the types of reports received, and the cooperative relationships the contractors build with each MedSun representative.

FDA believes the program is achieving the first objective of rapidly identifying and understanding information about problems with the use of medical

devices. Based on reports received in MedSun, FDA has published nine safety tips, issued a Public Health Notification, worked with a manufacturer to issue a Worldwide Market Withdrawal, and worked with two manufacturers to issue “Dear Doctor” letters explaining to health care providers the safest and most effective way to use a medical device. Many reports have been sent to FDA’s Office of Compliance to determine if regulatory action, such as an inspection of the manufacturing site, is warranted.

The reports are far superior in quality to those received from nonMedSun facilities (as noted by the FDA analysts responsible for reviewing adverse event reports). The longer the facilities are in the program, the better the reporters become. This outcome appears to be a direct result of the interaction the reporters have with the MedSun contractor during the initial follow-up that occurs after reports are submitted. The outcome also is influenced by the reminders they receive from other types of feedback supplied to them as part of the program.

FDA is learning about problems that have to be addressed by working with the device manufacturers. It also is learning about issues that probably require more long-term educational solutions that can be leveraged with professional organizations. FDA’s goal is to provide two such educational opportunities each year. An educational package that will address the safe and effective use of sutures and needles is currently under development.

The program also is achieving the second system objective, which is to provide a virtual laboratory for research into understanding device problems and adverse-event reporting. The MedSun sites will serve the purpose of such a virtual laboratory where participants can research and understand medical device problems and related information. Prior to implementation of MedSun, FDA did not share with medical facilities a relationship that would allow FDA to ask for their participation in surveys and studies. MedSun has allowed this type of relationship to form and grow. FDA’s goal was to be able to conduct surveys about device issues with at least a 70-percent response rate. Several surveys have been conducted with the MedSun hospitals to determine what, if any, usage problems occur with particular medical devices. All of the surveys had at least a 70-percent response rate (i.e., 70 percent of the sites that received the survey returned the survey with answers). In 2005, targeted surveillance research studies will be designed to improve reporting information obtained from specific departments of participating hospitals. The health professionals in those departments will be specifically trained to detect device-related problems. They will be asked to report all device related incidents, including “close-calls” through the facilities’ reporting systems. The MedSun representatives will send those reports to FDA.

The third objective, providing actionable feedback, is harder to evaluate. While a great deal of feedback is provided, it is not known how each site utilizes the information provided by FDA. To evaluate whether the feedback is useful, FDA in June 2003 conducted a survey of the MedSun representatives. The respondents were those representatives who had been in the program for at least one year and who were still in the program (116 people). Eighty-four

representatives responded to the survey (a 71-percent response rate). They were asked to rate the usefulness of the various types of tools and feedback we had provided. Most respondents rated MedSun News, recall information, safety alerts, and ECRI analysis as “useful” to “extremely useful.” More than half of the respondents rated the FDA Patient Safety News and the posters as “useful” to “extremely useful.”

The representatives also wrote comments. They reported that the feedback received in the newsletters, the interaction with the MedSun contractor, and the training tools provided have been useful in raising staff awareness regarding problems with medical devices. The risk managers reported that the more questions they ask their staffs about device problems, the more they learn about problems they did not know existed. Now they can be more proactive in addressing problems before they result in a serious adverse event.

## **Conclusion**

Developing and implementing a reporting system that is designed to have adverse event reports sent to FDA has been challenging. It takes numerous contractor and FDA resources to analyze the data that is generated by the program and to create useful feedback. It has been imperative for FDA to fully understand the barriers to reporting within the institutions and to motivating the institutions to send those reports to FDA. Each barrier must be addressed as extensively as possible. It is critical to provide staff with training to recognize events and to motivate them to report by letting them know their reports are important. It also is vital to provide useful feedback so patient safety may be improved. While FDA has no control over the reporting “culture” in MedSun facilities, it promotes a blame-free environment in order to encourage the reporting of deaths, serious injuries, and close-calls related to the use of medical devices. FDA encourages the MedSun reporters to send these types of reports by letting them know that others probably make similar errors. Furthermore, FDA explains to them that by more fully understanding what happened in a particular event, patient safety can be improved not only in their facility, but also in other facilities.

The success of this program depends upon the excellent relationship and trust the contractor builds with each MedSun representative. Such a relationship fosters meaningful communication about device problems between the contractor, FDA, and the reporting facilities. After 5 years of preliminary research, 2 years of data collection, and ongoing research, MedSun has been successful at recruiting, maintaining and motivating facilities to report to the program. FDA still has much to learn about encouraging reporting and about how to generate reports of uncommon events. It will continue developing research methods to evaluate these and other areas of interest.

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